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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,993	02/09/2004	Claudio Tonelli	07552.0025	1291

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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/775,993

Applicant(s)

TONELLI ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-146 is/are pending in the application.
- 4a) Of the above claim(s) 30-38, 41, 44-62 and 64-146 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29, 39, 40, 42, 43 and 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/13/04, 9/27/04, 10/4/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I in the reply filed on 17 July 2006 is acknowledged.
2. Claims 28-37, 44-62, and 64-146 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 July 2006.
3. Claim 41 is also withdrawn from consideration since it depends from nonelected claim 28.

### ***Claim Objections***

4. Claims 23, 24, 42, and 63 are objected to because of the following informalities: Applicant claims in line 1 that "it" comprises engagement connectors. Applicant fails to define what portion of the referenced support element that "it" refers to. For the purposes of examination, Examiner assumes that "it" refers to the support element as a whole. Appropriate correction is required.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-5, 20, 21, 23-26, 39, and 63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 20, and 21 of copending Application No. 10/771,536, and claim 6 of copending Application 10/771,415. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because, despite some variance in claim terminology, the claims of the copending applications recite all the limitations of the instantly presented claims (see US 2004/0162513, US 2004/0158190).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 12-23, 25-27, 39-40, 42-43, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,482,440 to Dennehey et al.

In the specification and figures, Dennehey discloses the device as claimed by applicant. With regard to claims 1-5 and 14, Dennehey discloses a support element or tray 26 for a blood treatment module or fluid circuit 18 comprising a basically plane or flat panel or wall 140 with rectilinear and continuous peripheral walls or side panels 138 that project away from the panel 140, creating a housing compartment and delimiting the sides of the panel or wall 140 (see column 10, lines 23-35, FIG 10). The panel 140 comprises sides (eg, 138) that are parallel and facing each other (see FIG 10).

With regard to claims 12 and 13, Dennehey illustrates that the peripheral walls 138 have a lip portion (unlabeled) at the bottom of the tray 26 that projects in a direction away from the side of the wall (see FIG 10).

With regard to claims 15, 17, and 63, Dennehey discloses that the main body 140 of the tray 26 comprises cut-outs or access openings (for example, 150A, 150B, 150C), that engage cassettes on the centrifuge or blood treatment assembly, disclosing that the tray is designed to be coupled to blood treatment machine 12 (see FIG 3, column 7, lines 7-14).

With regard to claims 18 and 19, Dennehey illustrates that the wall or panel 410 comprises sides 138 that are parallel and facing one another, wherein one side 138 comprises curved portions 146 placed between lengths of side 138, wherein the cavity of the curved portion faces an opposite side 138. The curved portion 146 is illustrated to comprise a round hole in the bottom of the portion, creating an opening for an outside element (drip chamber) that is concentric with the arc of the curved portion 146 (see FIG 10), thereby meeting the limitations of the claims.

With regard to claims 16, 22, and 40, Dennehey illustrates a rectangular box-like tray 26 that is "basically closed" by panel 140 and four side walls 138, closing the box on five of its six faces, meeting the limitations of the claims (see FIG 10). The box structure, when sectioned transverse to wall or panel 140, creates two C-shaped sections that meet the limitations of the claims.

With regard to claims 20 and 21, Dennehey discloses that the tray 26 may be made of PETG, which is well-understood in the art to be a mostly transparent plastic, or

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high-impact polystyrene, which is a stiff material, meeting the limitations of the claims (see column 10, lines 25-30, see also PETG specifications printed from internet on 7 Sept 2006, indicating well-known transparency of PETG).

With regard to claim 23, 25-27, Dennehey illustrates brackets 158 or engagement connectors that are continuous with, thereby fastened to, one rectilinear side wall 138, and continuous with body or panel 140 (see FIG 10). The brackets or engagement connectors comprise a u-shaped gap that extends from the top edge of the bracket towards the panel 140, creating a gap towards the housing compartment, meeting the limitations of the claims.

With regard to claim 39, Dennehey discloses and illustrates that the tray 26 or housing compartment houses a fluid circuit 18 that is designed to be housed in the tray (see FIGS 10-12, and entirety of columns 10-11).

With regard to claims 42 and 43, Dennehey illustrates regions 156 that are located within the tray or compartment 26 and extend from the panel or body 140. The regions 156 have recesses at the top that accommodate portions or lengths of tubing of the fluid circuit 18 (see column 11, lines 3-8, FIG 12).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6-11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,482,440 to Dennehey et al.

In the specification and figures, Dennehey discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of the location of the larger and smaller arced sections on the longer and shorter sides, respectively. With regard to claims 6-11, Dennehey illustrates that the panel 140 is delineated by shorter sides 138 that are rectilinear with respect to panel 140 and comprise large curved or arced sections 144 that face each other. Similarly, the longer opposite sides comprise smaller arced or curved sections 146 that face the opposite wall of panel 138. Applicant claims that the larger arcs are on longer sides of the support element, while the smaller arcs are on smaller sides of the support element.

However, Dennehey specifically discloses that the tray can be used with alternate blood processing machines that have different pump and tubing configurations (see column 11, lines 59-67). This disclosure in Dennehey is considered to suggest that the arrangement of tubes and pumps with respect to the walls of the tray or support element is a result-effective variable based on the type of processing machine in which the fluid circuit and support element is deployed. As such, the dimensions of the tray or support element and the location of the curved portions with regard to any given wall is optimized to accommodate the alternate processing machine. It has been held that the discovering an optimum value of a result effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, placing the curved portions of the tray or support element disclosed by Dennehey on a longer or shorter peripheral wall would



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necessarily be optimized to accommodate the pump and tubing structures of the alternate blood processing machines disclosed by Dennehey, rendering applicant's invention an obvious variation on the prior art.

With regard to claim 24, Dennehey illustrates brackets 158 or engagement connectors that are near the curved portions of the side walls, meeting the limitations of the claim (see FIG 10).

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

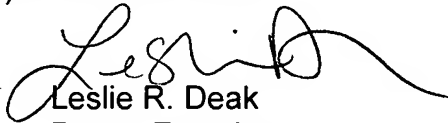
- a. US 4,637,813 DeVries
  - i. Fluid circuit support module with support plate and peripheral walls
- b. US 5,441,636 Chevallet et al
  - ii. Fluid circuit support module with plate 20 and peripheral walls
- c. US 6,589,482 Burbank et al
  - iii. Extracorporeal circuit with organizing tray

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Leslie R. Deak", with a stylized flourish extending to the right.

Leslie R. Deak  
Patent Examiner  
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7 September 2006